



UNITED STATES PATENT AND TRADEMARK OFFICE

20

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/488,728	01/20/2000	Anthony B Troutt	2623-B	4833

22932 7590 02/24/2005

IMMUNEX CORPORATION
LAW DEPARTMENT
1201 AMGEN COURT WEST
SEATTLE, WA 98119

EXAMINER

JIANG, DONG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/488,728	Applicant(s) TROUTT, ANTHONY B	
	Examiner Dong Jiang	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 15-17 and 19-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15-17 and 19-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

The request filed on 25 October 2004 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/488,728 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 25 October 2004 is acknowledged and entered. Following the amendment, claims 14 and 18 are canceled, claims 13 and 17 are amended, and new claims 19-28 are added.

Note: applicants indicate that claims 15 and 16 are "withdrawn", which is improper as applicant may *cancel*, but may not withdraw claims. Applicants are required, in response to the present Office Action, to clarify whether they intended to cancel the claims.

Currently, claims 13, 15-17 and 19-28 are pending and under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 14 and 18 are moot as the applicant has canceled or "withdrawn" the claims.

The enablement rejection of claims 13 and 17 under 35 U.S.C. 112, first paragraph is withdrawn in view of applicant's argument.

Formal Matters:

The specification is objected to for the following informalities, appropriate correction is required for each item:

On page 4, lines 9-10 of the third paragraph (amended), it recites that "soluble IL-17R comprises the signal peptide and the extracellular domain (residues 1-320 of SEQ ID NO:3)", however, SEQ ID NO:3 is a nucleic acid sequence, not a amino acid sequence.

Double Patenting Rejections:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

Art Unit: 1646

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13, 17 and 19-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5, 7, 11 and 17 of U.S. Patent No. 6,680,057 in view of Yu et al., U.S. Patent No. 6,406,867. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 1, 3, 5, 7, 11 and 17 of patent '057 are directed to a method for treating autoimmune disease with a soluble IL-17R protein comprising amino acids 1-320 of SEQ ID NO:10, an analog thereof with 80% sequence identity thereto, a fragment thereof, or a fusion protein thereof with a Fc or oligomerizing zipper domain, wherein the soluble IL-17R, analog, fragment or the fusion protein thereof binds IL-17. SEQ ID NO:10 of the patent represents the human IL-17R, and is 100% identical to SEQ ID NO:4 of the present application, and amino acids 1-320 of SEQ ID NO:10 represents the extracellular domain of the IL-17R. The method steps used in the method of the U.S. patent are the same to those in claims 13, 17 and 19-28 of the present invention, which is directed to a method of treating ulcerative colitis or Crohn's disease with a soluble IL-17R. Although the soluble IL-17R used in the claimed methods of '057 patent (a fragment comprising 1-320 of SEQ ID NO:10) is not identical to that in the present claims (a fragment comprising 28-320 of SEQ ID NO:4), they are not patentably distinct products because the fragment of 1-320 of SEQ ID NO:10 encompasses the fragment of 28-320 of SEQ ID NO:4. Further, '057 patent teaches clearly that the protein of SEQ ID NO:10 has an N-terminal signal peptide with a cleavage site between amino acid 27 and 28, and that soluble IL-17R comprises the signal peptide and the extracellular domain (residues 1-320 of

Art Unit: 1646

SEQ ID NO:10) or a fragment thereof (column 3, lines 16-20 and 28-30). Further, the same has been indicated in the present specification as that the protein of SEQ ID NO:4 has an N-terminal signal peptide with a cleavage site between amino acid 27 and 28, and that soluble IL-17R comprises the signal peptide and the extracellular domain (residues 1-320 of SEQ ID NO:4 ?) or a fragment thereof (page 4, the third paragraph). Furthermore, it is well established in the art that the signal peptide of a protein is cleaved in a natural setting, and it does not have a role in ligand binding. Therefore, clearly, the fragment comprising amino acids 1-320 of SEQ ID NO:10 of '057 patent, and the fragment comprising amino acids 28-320 of SEQ ID NO:4 of the present application would be considered equally exchangeable with respect to their IL-17 binding activity, and either one could be used as the effective ingredient in the method of patent '057 and the method of present invention.

The patent does not specifically define the term "autoimmune disease" as including ulcerative colitis and Crohn's disease, as that in the present claims.

However, it is known in the art that ulcerative colitis and Crohn's disease are autoimmune diseases, as evidenced by Yu et al. Yu teaches that autoimmune diseases may be divided into two general types, namely systemic and organ specific autoimmune diseases, and that autoimmune diseases include ..., autoimmune inflammatory bowel disease (including, e.g., ulcerative colitis and Crohn's disease), ... (column 108, lines 17-19, and 31-32). As such, ulcerative colitis and Crohn's disease recited in the present claims would be clearly embraced in "autoimmune disease" recited in claim 1 of '057. Therefore, the conflicting claims are not patentably distinct from each other.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1646

Claims 13, 17 and 19-28 are rejected under 35 U.S.C. 103(a) as being obvious over Yao et al., U.S. Patent No. 6,680,057 in view of Yu et al., U.S. Patent No. 6,406,867, for the same reasons addressed above.

The applied reference U.S. Patent No. 6,680,057 has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by:

(1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15 and 16 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, for the reasons of record set forth in the previous Office Actions mailed on 31 July 2001, and 17 May 2002.

No argument made in applicants response toward this rejection.

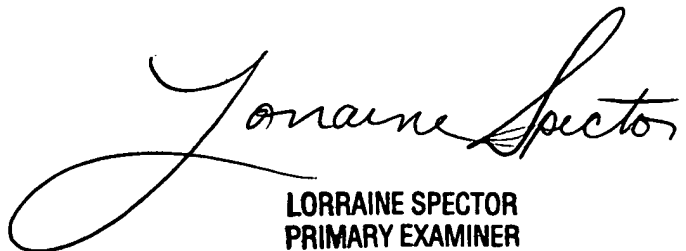
Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
1/30/05